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TITLE: The Economic and Quality of Life Impact of Remote Technologies on High Risk Patients and Their Caregivers

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14. ABSTRACT
The chronically ill have complex healthcare needs and require a disproportionate share of medical resources. We conducted a pilot study (CLIN001) to determine whether home-based preventative care improves healthcare outcomes with a randomized trial intervention in high-risk dialysis patients utilizing either a home health aide (HHA) or clinical measurements made by the patient at home using remote technology (RT). Over the first nine months, hospitalizations, emergency room visits, and associated charges were significantly lower in the RT group. CLIN0002 eliminates the HHA group and seeks to further explore the stability of these patterns over time in a larger sample of patients. The results from the 44 patient participating in CLIN0002 showed significant differences in health outcomes including number of days of hospitalization, prorated healthcare charges, and continued self reliance of the RT participants. RT can play an important role in improving health outcomes of patients with complex healthcare needs, and may be economically sustainable.

15. SUBJECT TERMS
Remote Technologies; Cost Effectiveness; High-Risk Patients; Caregivers; Dependent Care

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The Economic and Quality of Life Impact of Remote Technologies on High Risk Patients and Their Caregivers

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INTRODUCTION:

The care of patients disabled from chronic disease is costly--not only in terms of increased medical expenditures and loss of productivity, but for caregivers, who are more likely to report increased levels of stress. Improved health outcomes using remote technologies have been demonstrated; however, convincing cost-effective analyses have been lacking, and relief of caregiver burden is uncertain. We carried out a pilot study, CLIN 0001, testing a patient and caregiver-centered Plan of Care (POC) utilizing remote technologies (RT) or a program of home health assistance by Home Health Aides (HHA) compared to a control group of similar patients receiving Usual Care (UC) or optimal dialysis care. Data from the nine-month pilot study suggested that the RT may offer substantial cost savings and improved intermediate health outcomes. CLIN 0002 was designed to focus resources on the RT intervention and explore the stability of these patterns over time and to demonstrate sustainability.

BODY:

During the past 12 months, a no-cost extension of one quarter was granted to CLIN 0002 on December 2009 (see Appendix 1: Amendment of Solicitation/Modification of Contract, dated December 7, 2009). The period of performance for CLIN0002 was extended from 20 December 2008 – 19 January 2010 to 20 December 2008 – 19 May 2010. The approval incorporates the revised budget for CLIN0002 dated 25 November 2009. Study interventions with this pilot study group were concluded and hospitalization records, survey data, etc. were analyzed.

A Continuation Modification was submitted to USAMRMC on January 15, 2010 and was approved on May 28, 2010 (see Appendix 2: Amendment of Solicitation/ Modification of Contract, dated May 26, 2010). Recruitment effort for CLIN0003 took place and continues with the support of Liberty Dialysis staff. Study equipment has been purchased and preparations are being made to install the Turtle units in the homes of study participants.

The status of each task in the approved Statements of Work for CLIN 0002 and CLIN 0003 follows.

STATEMENT OF WORK (CLIN 0002):

Task 1. Conduct all appropriate procedures with institutional review boards (3 months).

Completed.

- March 3, 2009: Project protocol, informed consent form and supporting documents were submitted to the Western IRB at the request of the HPH IRB. (HPH IRB transferred all research studies it oversaw to Western IRB).
- April 17, 2009: Western IRB issued approval for all study documentation. It was determined that HPH IRB had erroneously submitted an old version of the protocol on our behalf, so the newest version was submitted (see Appendix 3: Western IRB Approval Letter dated April 17, 2009).
- May 22, 2009: Western IRB issued approval for all study documentation (see Appendix 4: Western IRB Approval Letter dated May 22, 2009)
- July 10, 2009: Western IRB issued its approval of Protocol version 9, a revised consent form, and two study advertisement (see Appendix 5: Western IRB Approval Letter dated July 10, 2009, Appendix 6: Consent form and Appendix 7: Study advertisement).
- July 29, 2009: HRPO Issued an approval for the continuing review report for the subject protocol that had been submitted in November 2008 (see Appendix 8: HRPO Amendment and Continuing Review Acceptance Memorandum dated July 29, 2009). Karen Eaton of HRPO explained that

though the protocol had been approved, there was an unexplained delay sending it to the H.O.P.E. Project office.

- August 7, 2009: After reviewing Protocol version 9, Karen Eaton said that the St. Francis Healthcare Foundation had to update their Federalwide Assurance information. In addition, Western IRB needed to approve some minor corrections to wording in the protocol.
- September 16, 2009: Submitted Protocol, version 10, dated September 14, 2009 to WIRB.
- September 18, 2009: Western IRB issued its approval of Protocol version 10 (see Appendix 9: WIRB Approval, dated September 18, 2009).
- September 25, 2009: HRPO issued an approval of the amendments to the Protocol version 10 (see Appendix 10: HRPO Amendments Apprlval Memorandum, dated September 25, 2009).

Task 2. Recruit Patients

Completed.

Study personnel made numerous visits to the Liberty Dialysis sites (Kaimuki, Leeward, Siemsen, Sullivan, Waipahu and Waianae) to meet with and consent potential study participants. Principal Investigator met with local nephrologists to discuss the Pilot Study results in order to garner their support in our recruitment efforts. The Remote Care Coordinator met with 106 patients at the various facilities. 53 patients signed consent forms to participate. Recruitment efforts for CLIN0002 continued until November 2009 because new patients were recruited as needed when several patients withdrew their participation for a variety reasons. Five withdrew at the request of nephrologist, Two death, one problem with DSL installation problem, one son did not want father to participate, one withdrew due to cancer diagnosis, one opted out, one moved off island (Samoa), and one was removed for noncompliance. On November 13, 2009, the last patient signed the consent.

Task 3. Populate research database.

- **Review medical records and enter selected information into database.**
- **Rank patient using Risk Score tool.**

Completed. Consented patients were ranked based on their Risk Score to determine whether they qualify to be part of the study. Patients with high Risk Scores (Risk Score ≥ 1.2) had their medical records for hospitalizations collected.

Task 4. Enroll patients (N=50) and caregivers into study.

Completed.

More than 100 patients expressed interest in the study and 53 signed the consent forms to participate in the study. Of these patients, 38 were identified as having a Risk Score that qualified them for a positioning the study. They were randomly selected and placed into either the RT group or the Control Group. 29 new patients enrolled to phase 2 of the study. Five of these patients were not selected at the request of their nephrologist. Other patients were not selected for a variety of reasons, including DSL connection problems, moving off the island, cancer diagnosis, having changed their mind, being incoherent, drug seeking behavior and so forth. One patient passed away.

The Principal Investigator decided that it would be helpful to continue monitoring CLIN 0001 RT and Control Group patients, if they were in favor of staying in the study beyond the agreed upon 9 months. On July 10, 2009, Western IRB issued an approval for the revised consent form which lengthen the study participation from 9 months to an additional 24 months. All of the RT and Control Group patients from the Pilot Study were approached about continuing their participation in the study in Phase 2. Of the Pilot Study patients who were approached about continuing their involvement with the study in Phase 2, eight RT patients signed updated consent forms to continue and one passed away. Of the Pilot Study Control Group, five patients signed updated consent forms to continue, one patient passed away and four declined further participation.

Data were collected on total 44 patients. Due to death and drop out, at conclusion, 16 patients are in RT Group and 20 patients are in Control Group.

Task 5. Install and use a Health Insurance Portability and Accountability Act (HIPPA) compliant telehealth home health monitoring system.

- **Monitoring 25 patients on the island of Oahu who meet inclusion criteria and are enrolled in the experimental group.**
- **Monitor physiologic parameters and symptoms of patients based on customized care plans developed at the time of patient enrollment.**
- **Utilize synchronous video-teleconferencing to provide consultative services between a Care Manager, patients and caregivers.**

Completed.

The RCC and IT specialist set up the Turtle 500 from ViTel Care for use by the study participants. Virtually, all new Turtle 500 monitors that were shipped to the H.O.P.E. Project by ViTel Net were found to be defective. The problems were discovered when the RCC attempted to set up the equipment in patients' homes. The Turtle 500's were returned to ViTel Net and replacements were shipped to the H.O.P.E. Project. ViTel Net also sent an IT representative to fix any problems with the equipment. The initial problems caused a delay in the start of the patient monitoring. The first patient's remote technology was installed in his home on July 27, 2009. Continuing RT patients from Pilot Study had their remote technology replaced by new, smaller Turtle 500's.

Task 6. Conduct phase 2 of the study of patients.

- **Develop and test study database.**
- **Gather and enter relevant patient information into database.**
- **Identify potential subjects using Risk Score stratification.**
- **Recruit, consent, and enroll patients and caregivers.**
- **Deliver Remote Technology services to study cohort of 20 patients using home monitors and video teleconferencing.**
- **Collect data on hospitalization, emergency room utilization, antibiotic use, and fiscal charges on patients.**

Completed.

Healthcare personnel are proficient in the use of the remote technologies. Patients and caregivers were trained in the use of the Turtle monitors and the units were installed in their homes. Follow up training was provided as needed.

Medical records and hospital charges were collected quarterly for all new Phase 2 patients after they have been in the study one quarter. Continuing patients from the Pilot Study had their medical records gathered from the hospitals quarterly as well. They were retrieved for all patients monthly from April 2010. These were reviewed by study personnel and entered into the database.

Task 7. Deliver clinical interventions to the study population.

Completed.

Interventions for RT patients began as soon as their turtle monitoring equipment is installed in their homes. All RT patients sent their data in to the RCC three to four times a week.

Data collection for Control Group patients began July 15, 2009. As for those who consented before July 14, 2009, medical records from the past five years (from July 15, 2004 to July 14, 2010) were retrieved for Phase 2 patients. As for those patients who consented after July 15, 2010, past five years of medical records were requested for their file as well. These were reviewed by study personnel to gain insights into the health histories and issues of the study participants. Quarterly medical records and hospitalization charges for these patients were retrieved after they have been in the study a month since July 15. 2010.

Task 8. Create home Electronic Medical Records (HEMR) access for patient's physician.

Completed.

Study patients' nephrologists and their staff were trained to use HEMR.

Task 9. Administer quality of life (SF-36) and satisfaction of service (CSQ-8) surveys.

Completed.

SF36 (see Appendix 11: SF-36) and Health Utilities Index (HUI) (see Appendix 12: HUI) surveys were administered to all study participants at the beginning (August to November 2009) and at the midpoint (January to February 2010). CSQ8 surveys were given at the midpoint (October 2009) to the RT patients from the Pilot Study in order to measure their satisfaction with the service they received. CSQ8 surveys were also mailed home for patient caregivers to fill out and return at this time. CSQ survey was administered to 7 RT Pilot Study patients. 7 surveys were sent to their caregivers and 6 out of 7 surveys were returned. CSQ Surveys for the Phase 2 patients is in the process of being administered. As for Physician Satisfactory Survey, the patients' primary physician will be given these at the very end of the study.

Task 10. Conduct analysis (3 months).

- **Health resource utilization outcomes of RT compared to UC.**
- **Economic cost effectiveness of RT compared to UC.**
- **Impact of interventions on quality of life of patient (SF-36).**
- **Impact of interventions on caregiver satisfaction with services (CSQ-8).**

Ongoing.

Preliminary analysis of the study data is included later in this section. Dr. Berman and Dr. Halliday completed their research paper detailing their analysis of the Pilot Study results. It was submitted for publication in Clinical Journal of American Society of Nephrology (CAJSN) as an expedited report. However, it was rejected due to small sample size. They are in the process of revising their research paper detailing their analysis of the Phase 1 plus Phase 2 results and it is being submitted to the same journal.

STATEMENT OF WORK (CLIN 0003):

Task 1. Obtain Institutional Review Board (IRB) approval for continuation of study.

Completed/Ongoing.

- February 17, 2010: A Continuing Review Report was submitted to the Western IRB.
- March 26, 2010: Western IRB Issued approval of the Continuing Review. (See Appendix 13: Western IRB Approval Letter dated March 31, 2010).

- April 30, 2010: A Western IRB Continuing Review Report and Approval documents were submitted to HRPO.
- May 18, 2010: the H.O.P.E. Project received the approval (See Appendix 14: HRPO Amendment and Continuing Review Acceptance Memorandum, dated May 18, 2010).
- The Protocol version 11 is being submitted to the Western IRB and HRPO within the next month.

Task 2. Recruit patients.

Ongoing.

The Remote Care Coordinator (RCC) is in the process of meeting with and discussing the study with potential participants at the Liberty Dialysis Waipahu, Kaimuki, Leeward, and Waianae sites as well as Sullivan and Siemsen Liberty Dialysis site. Liberty Dialysis staff members and nephrologists assisted in recommending patients who would like to find out more about the study. The RCC made numerous visits to the facilities to discuss the study with the patients and assist in consenting them to participate. As of June 20, 2010, 57 patients consented to participate, 43 of whom were found out to have high Risk Score (Risk Score ≥ 1.2). Of the 43, 39 were randomly selected and placed into either the RT group or the Control Group. As of June 20, 2010, 17 patients are assigned to RT group, 22 were assigned to Control Group and 2 were assigned to Back-up Group. The other 4 patients declined to participate either before or after randomization due to various reasons, including changing their mind, their caregivers do not want patients to participate and so forth.

Some of the RT and Control Group patients from the Phase 2 were approached about continuing their participation in the study. Those who agreed signed revised Informed Consent Forms approved by Western Institutional Review Board (IRB) that lengthen their monitoring time from nine months to 24 months. One patient withdrew at this time.

As of June 20, 2010, 16 RT Group patients and 20 Control Group patients from Pilot Study and Phase 2 are currently monitored for CLIN0003 and intervention and data collection for Phase 3 new patients has not started yet. Data collection for 22 Control Group patients from Phase 3 will start on July 1, 2010. Interventions for 17 new RT patients for Phase 3 will begin as soon as their remote monitoring equipment is installed in their homes.

Task 3. Populate research database.

- **Review medical records and enter selected information into database.**
- **Rank patients using Risk Score tool.**

Ongoing.

Consented patients were ranked based on their Risk Score to determine whether they qualify to be part of the study. Patients with high Risk Scores will have their medical records for hospitalizations collected within the next month.

Task 4. Enroll patients (N=40) and caregivers into study.

Ongoing.

As of June 20, 2010, the RCC has met with approximately 89 patients who have expressed interest in the study. Of those, 57 patients signed consent forms to participate in the study, and 43 meet the criteria to participate.

Task 5. Install and use a Health Insurance Portability and Accountability Act (HIPAA) compliant telehealth home health monitoring system.

- **Monitor 40 patients on the island of Oahu who meet inclusion criteria and are enrolled in the experimental group.**
- **Monitor physiologic parameters and symptoms of patients based on customized care plans developed at the time of patient enrollment.**
- **Utilize synchronous video-teleconferencing to provide consultative services between a Care Manager, patients and caregivers.**

Ongoing.

The RCC and IT specialist are in the process of setting them up for use by the study participants. H.O.P.E. Project will purchase 10 Turtle 500 units from ViTel Net within the next month.

Task 6. Deliver clinical interventions to the study population.

Ongoing.

Subjects are being trained in the use of the Turtle monitors and the units in the process of scheduling their turtle installation in their homes. This includes ongoing monitoring of 16 patients already enrolled in the study from Phase 1 and 2.

Task 7. Create Home Electronic Medical Records (HEMR) access for patient's physician.

Ongoing.

Study patients' nephrologists and their staffs are being trained to use HEMR. This is a continuation of the methodology used in CLIN 0001 and 0002.

Task 8. Conduct telehealth research described in the hypotheses and the design.

- **Measure the described clinical and economic outcomes in the study population.**
- **Administer Quality of Life (QoL) and self-efficacy surveys to patients and caregivers at the beginning, midpoint and end of the study.**
- **Conduct statistical analyses.**
- **Perform a comprehensive economic analysis.**

Ongoing.

Now that the 39 study participants have been selected and consented, the telehealth research will begin. Baseline surveys are in the process of being administered. Medical records from the past five years will be retrieved within the next month and will be reviewed by study personnel to gain insight into the health histories and issues of the study participants. Hospitalization records will be accessed after they have been in the study a month. Continuing patients from Phase 1 and 2 have had their hospitalization records retrieved monthly. Analyses will be conducted once data are collected.

ANALYSIS OF CLIN 0002 (PHASE 2) RESULTS

I. Data and Methods

The data come from 44 patients who were enrolled in a Randomized Controlled Trial (RCT). We collected data on hospital and emergency room visits, hospital days, and total charges. For in-patient services, the health utility indices 2 and 3 (HUI2 and HUI3, respectively), the SF-36, and the patient's risk score (at baseline) and every 6 months or when the patient dropped out of the study. We report the p-values of these tests in Table 2. We compute the Cost-Effectiveness Ratio as

$$CE = \frac{\overline{C}_1 - \overline{C}_0}{\overline{E}_1 - \overline{E}_0},$$

where $\overline{C}_1$ and $\overline{C}_0$ are total average costs and $\overline{E}_1$ and $\overline{E}_0$ are average Quality Adjusted Life Years (QALY) in treatment and control per person over the study period. QALY are measured by summing either the HUI2 or HUI3, weighted by the percentage of the year they measured over the three rounds. So, if u_r denotes the average health utility for round r, then we will have that

$$QALY = \sum_{r=1}^{3} u_r / 4,$$

as each three-month round represents one quarter of a year. Because the Pilot Study spanned only nine months, we did not discount costs. We used the delta-method to compute the standard error of the CE Ratio.

We begin with

$$\begin{pmatrix} \overline{C}_1 - \overline{C}_0 \\ \overline{E}_1 - \overline{E}_0 \end{pmatrix} \overset{A}{\sim} N\left(\begin{pmatrix} C_1 - C_0 \\ E_1 - E_0 \end{pmatrix}, \Sigma \right),$$

where

$$\Sigma = \begin{pmatrix} \sigma_C^2 / N & \sigma_{CE} / N \\ \sigma_{CE} / N & \sigma_E^2 / N \end{pmatrix}$$

and

$$\begin{aligned} \sigma_C^2 &= \sigma_{C_1}^2 + \sigma_{C_0}^2 \\ \sigma_E^2 &= \sigma_{E_1}^2 + \sigma_{E_0}^2 \\ \sigma_{CE} &= \sigma_{C_1 E_1} + \sigma_{C_0 E_0} \end{aligned} .$$

Define the mapping as

$$f(a,b) = \frac{a}{b}.$$

Then, we will have that

$$\nabla f(a,b) = \begin{pmatrix} \frac{1}{b} & -\frac{a}{b^2} \end{pmatrix}.$$

The delta method gives us that

$$CE \overset{A}{\sim} N\left(\frac{C_1 - C_0}{E_1 - E_0}, \sigma_{CE}^2 \right),$$

where

$$\sigma_{CE}^2 = \nabla f(C_1 - C_0, E_1 - E_0) \Sigma \nabla f(C_1 - C_0, E_1 - E_0)^T .$$

Applying the analogy principal, we obtain that

$$\sigma_{CE}^2 = \left(\sigma_C^2 + CE^2 \sigma_E^2 - 2CE\sigma_{CE} \right) / \left(\overline{E}_1 - \overline{E}_0 \right)^2 .$$

If we take the square root of the above equation, we obtain the standard error.

II. Results

Demographics

Of the 89 patients who gave informed consent for CLIN 0001 and CLIN0002, 66 met the criteria of high risk utilizing the Risk Score calculated from the data in their medical records. Forty-four (44) patients were included in the analysis (UC, n=25; RT, n=19) conducted on each patients records from time of enrollment through March 31, 2010 (Table 1). Of 22 patients not enrolled in the study, 2 were withdrawn because they could not master the technology of RT, 3 patients were not compliant. The remainder declined when assigned to a limb of the study that did not interest them. The mean age was 62 for UC, 56.21 for RT, Risk Scores, Karnofsky score, and the number of study days was similar in both groups as was the SF36 and subscales Physical Component Summary (PCS),

Mental Component Summary (MCS) and the Quality of Life (QALY) (Table 1).

Outcomes

The total number of study days for the UC group was 8352 days and 6711 days for the RT group. The RT group had better health outcomes (Table 1). The number of hospital days per study day was significantly less in the RT limb (0.0087 vs. 0.036) (p< .0567). Total hospital and emergency room charges/ patient day of study in the RT group ($62.97/day) were 26% of the charges in the UC group ($245.36) (p<. 0277). Quality of Life (QOL) as a measure did not improve in the RT group, and did not deteriorate in the UC group, despite the disparity in clinical outcomes (Table 1).

Patient – Clinician interaction.

In the RT intervention group, the number of nurse clinician-initiated contacts for outlier clinical values or subjective change in clinical condition as reported remotely by the patient decreased from 23 in the first month of each patients intervention to less than 5 episodes by 6 months of involvement. During the same period, the number of contacts for technical issues did not change (Figure 1).

III. Conclusions

The findings that RT can have a positive impact on health outcomes and potentially pay for itself through cost savings is of great interest when the future portends increasing number of patients with chronic diseases combined with frailty and disability. CLIN0002 reinforced the findings of the pilot study. However, the sample size is still very small. We project that a total of 80 to 100 patient years will be required to power the analysis so that the results can impact public policy and the delivery of healthcare.

Table 1. Healthcare Resource Outcomes

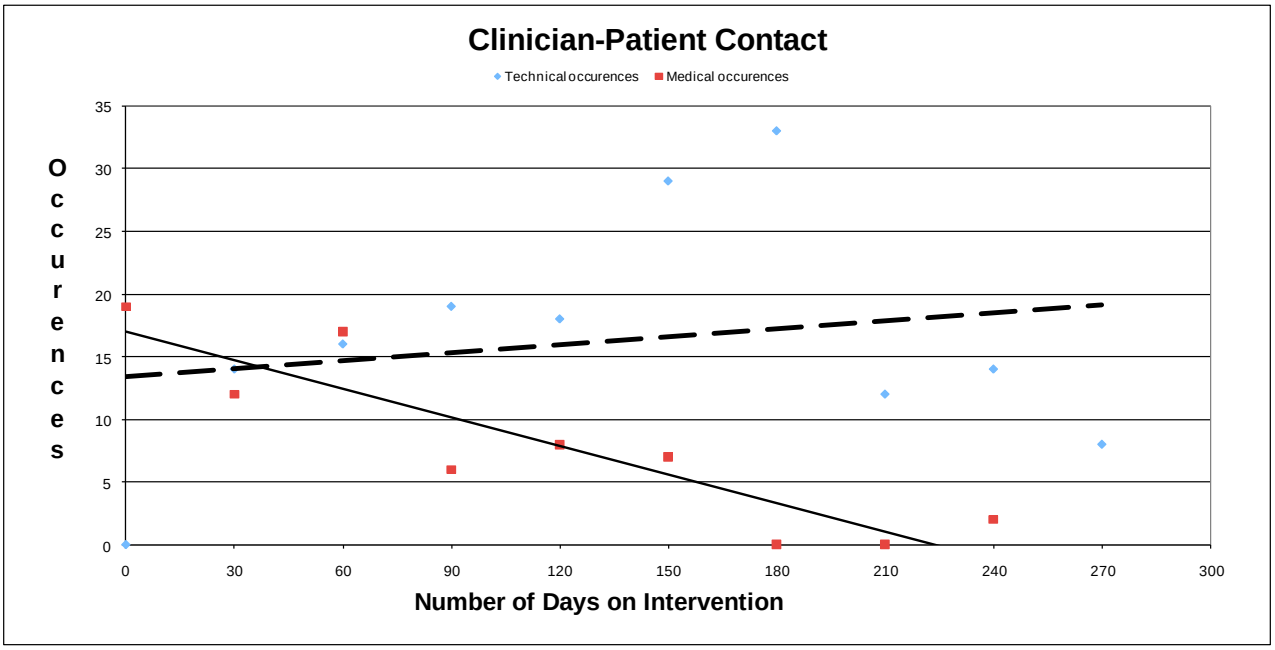
	UC N=25 Mean (SD)	RT N=19 Mean (SD)	t (RT – UC) [p-value]
Age	62 (14.46)	56.21 (11.93)	-1.42 [0.1642]
Risk Score	1.35 (0.11)	1.42 (0.16)	1.68 [0.1002]
K-score	57.6 (5.23)	58.95 (3.15)	0.99 [0.3264]
Total Study Days	334 (202.64)	353 (208.40)	.306 [.38]
Hospital Visit per Patient Day	0.0062 (0.0060)	0.0031 (0.0070)	-1.56 [0.1257]
Hospital Days per Patient Day	0.036 (0.057)	0.0087 (0.024)	-1.96 [0.0567]
ER Visits per Patient Day	0.0018 (0.0031)	0.0013 (0.0028)	-0.55 [0.5855]
Charges per Patient Day	$245.36 (321.85)	$62.97 (151.44)	-2.28 [0.0277]
PCS[1]	38.22 (8.30)	40.07 (7.90)	0.75 [0.4579]
MCS[2]	49.79 (8.60)	52.02 (9.47)	0.81 [0.4198]
QALY[3]	0.32 (0.26)	0.37 (0.25)	0.63 [0.5321]
CSQ-8 (Patients)	N/A	27.10 (3.85)	N/A
CSQ-8 (Caregivers)	N/A	27.81 (3.08)	N/A

Note:
1. PCS: Physical Component Summary.
2. MCS: Mental Component Summary
3. QALY: Quality of Life
4. Physician Satisfaction Survey: The patients' primary physician will be given these at the very end of the study.

Table 2: Reasons for Hospitalization

	UC (N=25)	RT (N=19)
Vascular Access Creation/Repair	25	7
Sepsis	10	2
Myocardial Infarct	2	1
Pneumonia	2	0
Fall Fracture	1	1
Hypotension	1	1
Diabetic Foot Infection	1	0
Misc. Surgery	9	2
Misc. Medicine	3	0

Figure 1. Patient-Initiated Contact Occurrences



KEY RESEARCH ACCOMPLISHMENTS:

- Recruited subjects for CLIN 0002. Met individually with over 106 patients who expressed interest in the study.
- Obtained signed consents from 53 patients.
- Applied Risk Score tool; 38 of the consented patients were determined to have high Risk Scores (.=1.2).
- Administered SF-36, HUI and CSQ8 surveys to all CLIN 0002 study participants.
- Collected and analyzed hospitalization records for study participants in CLIN 0002.
- Completed study interventions for RT and UC groups in CLIN 0002.
- Received IRB approval for all study documents and materials for CLIN 0003.
- Recruited subjects for CLIN 0003. Met individually with over 89 patients who expressed interest in the study.
- Obtained signed consents from 57 patients for Phase 3.
- Applied Risk Score tool; 43 of the consented patients were determined to have high Risk Scores (≥ 1.2) for Phase 3.
- As of June 20, 2010, 39 new patients enrolled in the study.

REPORTABLE OUTCOMES:

Based on the strength of the Pilot study and Phase 2 preliminary results, additional funding has been sought:

- 4/25/09: An application was submitted for a Recovery Act Limited Competition: National Institutes of Health Challenge Grant.
- 6/8/09: An application was submitted for a grant offered by the Agency for Healthcare Research and Quality Health Services Research Projects.
- 3/5/10: An amended application was submitted for a grant offered by Agency for Healthcare Research and Quality Health Services Research Projects, titled “Remote Health Technologies to Improve Outcomes for High-Risk Patients.” Due to the technical errors, it was resubmitted on July 2, 2010.
- 3/30/10: An application was submitted for a grant offered by the Agency for Healthcare Research and Quality Health Services Research Projects, titled “Change begins with H.O.P.E.: Reducing Healthcare-Associated Infections in Patient.”

CONCLUSION:

Results suggest that the use of telehealth monitors in the home with nurse case management oversight empowers patients. This in turn results in fewer

hospitalizations and emergency room visits and a lower per patient cost expenditure compared to a like group of patients without this intervention

CLIN 0003 continues to seek (1) further exploration into the stability of these patterns over time; (2) examination of how cost-savings relates to heath utility measures, such as quality adjusted life years; (3) how readiness to adopt technology influences patient trust; and (4) an assessment of whether these findings can be replicated in a larger sample of patients than in the Pilot Study and Phase 2.

CLIN 0003 of the study has enrolled and additional 39 patients who have been assigned to the Remote Technology or Usual Care (Control Group) limbs in a random fashion.

Appendices:

3. Western IRB Approval Letter dated April 17, 2009.
4. Western IRB Approval Letter dated May 22, 2009.
5. Western IRB Approval Letter dated July 10, 2009
6. Research Subject Information and Consent Form
7. Study Advertisements
8. HRPO Amendment and Continuing review Acceptance Memorandum dated July 29, 2009.
9. Western IRB Approval Letter dated September 18, 2009.
10. HRPO Amendments Approval Memorandum dated September 25, 2009.
11. SF36
12. HUI
13. Western IRB Continuing Review Approval Letter dated March 31, 2010.
14. HRPO amendment and Continuing Review Acceptance Memorandum dated May 18, 2010.

3. Western IRB Approval Letter dated April 17, 2009.

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Certificate of Approval

THE FOLLOWING WERE APPROVED:

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AMD. PRO. NUM:
TITLE:
THE ECONOMIC AND QUALITY OF LIFE IMPACT OF REMOTE TECHNOLOGIES ON HIGH RISK PATIENTS AND THEIR CAREGIVERS

APPROVAL INCLUDES:
Investigator
Protocol (06-24-2008) Version 6
Recruitment of Subjects Under the Grant #06167002 (The Economic and Quality of Life Impact of Remote Technologies on High Risk Patients and Their Caregivers)

Continued on Next Page...

WIRB APPROVAL IS GRANTED SUBJECT TO:
The Board requires that all subjects must be able to consent for themselves to be enrolled in this study.

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789
This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB). WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Full AAHRPP

Jan Vleck MD for
Theodore D. Schultz, J.D., Chairman

4/23/2009
(Date)

This document electronically reviewed and approved by Vleck, Jan on 4/23/2009 9:53:37 AM PST. For more information call Client Services at 1-360-252-2500

APPROVAL INCLUDES, Continued From Previous Page:

Consent Form [IN0]

Advertisement #6605449.0 We would like to tell - As Modified

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

- H.O.P.E. Project, Room B115, 2226 Liliha Street, Honolulu, Hawaii 96817

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.

    a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.

    b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB.

    c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

3. Obtain pre-approval from WIRB for any planned deviations that could adversely affect the safety or welfare of subjects, or the integrity of the research data and any changes in the research activity. The only exception is when changes are necessary to eliminate apparent immediate hazards to subjects. Immediately report to WIRB any such emergency changes implemented.

4. Promptly report to WIRB any new information that may adversely affect the safety of the subjects or the conduct of the trial.

    a. Report to WIRB all adverse events that are unanticipated and possibly related, within 10 days of the investigator becoming aware of them.

    b. Promptly report to WIRB other unanticipated problems involving risks to human subjects or others. These events do not readily fit the formal definition of Adverse Event, but could impact human subject safety and/or rights. Examples include theft of a computer containing private identifiable subject information, or study staff getting ill from inhaling a study agent.

    c. Provide reports to WIRB concerning the progress of the research, when requested.

5. Report to WIRB any unplanned protocol variance that could adversely affect the safety or welfare of subjects, or the integrity of the research data, within 10 days of becoming aware of the variance. Other unplanned variances may be recorded on a log and submitted with continuing review reports.

6. Ensure that prior to performing study-related duties each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

Contact	Company Name
Christine Nelson	Hawaii Pacific Health
Steven J. Berman M.D.	St. Francis Healthcare Foundation of Hawaii - H.O.P.E. Project
Stanley Saiki M.D.	Department of Defense

4. Western IRB Approval Letter dated May 22, 2009.

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Western Institutional Review Board ®

Certificate of Approval

(360) 252-2500
1-800-562-4789
FAX: (360) 252-2498

3535 SEVENTH AVENUE, SW, OLYMPIA, WA 98502-5010
P.O. BOX 12029, OLYMPIA, WA 98508-2029

THE FOLLOWING WERE APPROVED:

INVESTIGATOR: Steven J. Berman M.D.
Room B115
2226 Liliha Street
Honolulu, Hawaii 96817

BOARD ACTION DATE: 5/22/2009
PANEL: 6
STUDY APPROVAL EXPIRES: 4/17/2010
STUDY NUM: 1107395
WIRB PRO NUM: 20090577
INVEST NUM: 148923
WO NUM: 1-551664-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Annually

SPONSOR: Department of Defense
PROTOCOL NUM: None
AMD. PRO. NUM:
TITLE:
THE ECONOMIC AND QUALITY OF LIFE IMPACT OF REMOTE TECHNOLOGIES ON HIGH RISK PATIENTS AND THEIR CAREGIVERS

APPROVAL INCLUDES:
Client Satisfaction Questionnaire #6733935.0 - As Submitted
Data Collection - Medical Records Form #6733929.0 - As Submitted
Remote Technology Monitoring #6733930.0 - As Submitted
Revised Protocol (03-13-2009) Version 8-2

Continued on Next Page...

WIRB APPROVAL IS GRANTED SUBJECT TO:
RE-CONSENTING INSTRUCTIONS: All subjects who will be enrolled in the future for this study must sign the most current WIRB-approved consent form(s).

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789
This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB). WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Full AAHRPP Accreditation

Robert A Taylor as for
Theodore D. Schultz, J.D., Chairman

5/27/2009
(Date)

This document electronically reviewed and approved by Taylor, Robert on 5/27/2009 9:55:45 AM PST. For more information call Client Services at 1-360-252-2500

APPROVAL INCLUDES, Continued From Previous Page:

Revised Protocol (10-03-2008) Version 7

Consent Form [IS0]

Advertisement #6605449.1 We would like to tell - As Submitted

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

- H.O.P.E. Project, Room B115, 2226 Liliha Street, Honolulu, Hawaii 96817

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.

    a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.

    b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB.

    c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

3. Obtain pre-approval from WIRB for any planned deviations that could adversely affect the safety or welfare of subjects, or the integrity of the research data and any changes in the research activity. The only exception is when changes are necessary to eliminate apparent immediate hazards to subjects. Immediately report to WIRB any such emergency changes implemented.

4. Promptly report to WIRB any new information that may adversely affect the safety of the subjects or the conduct of the trial.

    a. Report to WIRB all adverse events that are unanticipated and possibly related, within 10 days of the investigator becoming aware of them.

    b. Promptly report to WIRB other unanticipated problems involving risks to human subjects or others. These events do not readily fit the formal definition of Adverse Event, but could impact human subject safety and/or rights. Examples include theft of a computer containing private identifiable subject information, or study staff getting ill from inhaling a study agent.

    c. Provide reports to WIRB concerning the progress of the research, when requested.

5. Report to WIRB any unplanned protocol variance that could adversely affect the safety or welfare of subjects, or the integrity of the research data, within 10 days of becoming aware of the variance. Other unplanned variances may be recorded on a log and submitted with continuing review reports.

6. Ensure that prior to performing study-related duties each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

Contact	Company Name
WIRB Translations Department	WIRB USA
Christine Nelson	Hawaii Pacific Health
Steven J. Berman M.D.	St. Francis Healthcare Foundation of Hawaii - H.O.P.E. Project
Stanley Saiki M.D.	Department of Defense
Heather Thomas	St. Francis Healthcare Foundation of Hawaii - H.O.P.E. Project

5. Western IRB Approval Letter dated July 10, 2009

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Western Institutional Review Board ®

Certificate of Approval

(360) 252-2500
1-800-562-4789
FAX: (360) 252-2498

3535 SEVENTH AVENUE, SW, OLYMPIA, WA 98502-5010
P.O. BOX 12029, OLYMPIA, WA 98508-2029

THE FOLLOWING WERE APPROVED:

INVESTIGATOR: Steven J. Berman M.D.
Room B115
2226 Liliha Street
Honolulu, Hawaii 96817

BOARD ACTION DATE: 7/10/2009
PANEL: 6
STUDY APPROVAL EXPIRES: 4/17/2010
STUDY NUM: 1107395
WIRB PRO NUM: 20090577
INVEST NUM: 148923
WO NUM: 1-561266-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Annually

SPONSOR: Department of Defense
PROTOCOL NUM: None
AMD. PRO. NUM:
TITLE:
THE ECONOMIC AND QUALITY OF LIFE IMPACT OF REMOTE TECHNOLOGIES ON HIGH RISK PATIENTS AND THEIR CAREGIVERS

APPROVAL INCLUDES:

Advertisement #6911938.0 Benefits you become an active - As Submitted
Revised Protocol (07-01-2009) Version 9
Consent Form [IN1]
Advertisement #6911937.0 HOPE Project Start you are - As Modified

WIRB APPROVAL IS GRANTED SUBJECT TO:

RE-CONSENTING INSTRUCTIONS: All subjects currently enrolled in this study must sign the most current WIRB-approved consent form(s) at their next visit. Subjects enrolled in the future must sign the most current WIRB-approved consent form(s).

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789

This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB), OHRP/FDA parent organization number IORG 0000432, IRB registration number IRB00000533. WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Full AAHRPP Accreditation

Robert A Taylor DO for
Theodore D. Schultz, J.D., Chairman

7/16/2009
(Date)

This document electronically reviewed and approved by Taylor, Robert on 7/16/2009 11:10:39 AM PST. For more information call Client Services at 1-360-252-2500

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

- H.O.P.E. Project, Room B115, 2226 Liliha Street, Honolulu, Hawaii 96817

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

3. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate. (Due to the unique circumstances of research conducted at international sites outside the United States and Canada where WIRB approved materials are translated into the local language, the following requirements regarding consent forms bearing the WIRB approval stamp and regarding certification of translations are not applicable.)

    a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.

    b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB.

    c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

4. Obtain pre-approval from WIRB for changes in research.

5. Obtain pre-approval from WIRB for any planned deviations that could adversely affect the rights, safety or welfare of subjects, or the integrity of the research data and any changes in the research activity. The only exception is when changes are necessary to eliminate apparent immediate hazards to subjects. Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days.

6. Promptly report to WIRB all unanticipated problems (adverse events, protocol deviations and violations and other problems) that meet all of the following criteria:

    a. Unexpected (in terms of nature, severity or frequency);

    b. Related or possibly related to participation in the research; and

    c. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

    Please go to www.wirb.com for complete definitions and forms for reporting.

7. Provide reports to WIRB concerning the progress of the research, when requested.

8. Ensure that prior to performing study-related duties, each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

Contact	Company Name
Christine Nelson	Hawaii Pacific Health
Steven J. Berman M.D.	St. Francis Healthcare Foundation of Hawaii - H.O.P.E. Project
Stanley Saiki M.D.	Department of Defense
Heather Thomas	St. Francis Healthcare Foundation of Hawaii - H.O.P.E. Project

6. Research Subject Information and Consent Form

APPROVED
AS MODIFIED
Jul 10, 2009
WIRB®

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	THE ECONOMIC AND QUALITY OF LIFE IMPACT OF REMOTE TECHNOLOGIES ON HIGH RISK PATIENTS AND THEIR CAREGIVERS
PROTOCOL NO.:	None WIRB® Protocol #20090577
SPONSOR:	Department of Defense Ft. Detrick, Maryland United States
INVESTIGATOR:	Steven J. Berman, M.D. Room B115 2226 Liliha Street Honolulu, Hawaii 96817 United States
SITE(S):	H.O.P.E. Project Room B115 2226 Liliha Street Honolulu, Hawaii 96817 United States
STUDY-RELATED PHONE NUMBER(S):	Steven J. Berman, M.D. 808-547-6208

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may have an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

You are asked to participate in a research study conducted in your home by Dr. Steven J. Berman in cooperation with Liberty Dialysis and your nephrologist. Your participation in this study is voluntary. You should read the information below and ask questions about anything you do not understand before deciding whether or not to participate.

Date of preparation of current version: 7 January 2009

PURPOSE OF THE STUDY

The purpose of the study is to look at two different ways of monitoring dialysis subjects:

1. Home Monitoring using teleconferencing with oversight by a nurse who works from a remote location ("Home Remote Monitoring").
2. The usual care associated with the dialysis center.

We will measure the effect of the Home Remote Monitoring on health by the need for hospitalization, emergency room visits, the quality of life, and caregiver's satisfaction.

SPONSORSHIP

The research study is sponsored by the Department of Defense.

DURATION OF PARTICIPATION

Your participation will last for nine months and may be extended an additional 24 months. If you require hospital or emergency room care, information will be collected from the medical and billing departments for an additional year.

NUMBER OF VOLUNTEERS

There will be 50 subjects in the study.

PROCEDURES

If you agree to be considered to be in the study and sign this consent form, your medical record will be reviewed and you may be asked to be a study subject. Twenty five subjects will be assigned to Home Remote Monitoring, and twenty five subjects will receive the same care you currently receive. As there are only 50 participating in the study, you may be asked to participate if one of the other subjects drops out of the study. You will be assigned to one of two groups by random chance (like flipping a coin). You or your study doctor will have no choice as to your group assignment.

If you are assigned to the Home Remote Monitoring group, a plan of care will be created for you by a team consisting of yourself, your caregiver (as applicable), your nephrologist, and the research staff.

If you are assigned to the Home Remote Monitoring group, the plan of care will determine which home monitoring equipment would be most helpful for you. The monitoring devices are capable of measuring weight, blood pressure, blood sugar, and vascular access function, and include a video conferencing unit that will upload these measurements to the nurse. All of the equipment will be tested in your home with training until you or your caregiver is confident in its use. If there are new abnormalities, the nurse will contact you. You and your caregiver may discuss the

issue with the nurse using the teleconferencing equipment. The nurse will not make home visits, but will be in contact with your study doctor to determine the urgency of an office or emergency room evaluation.

If you are assigned to the control group, you will receive the same care that you currently receive. Additionally, a research nurse will review your dialysis records to be sure that you continue to receive optimal dialysis care, and will collect information if you require hospitalization or an emergency room visit.

To evaluate the effect of the study on your quality of life, you will be asked to complete four simple questionnaires three times during the study. It will take you about 30 minutes to complete the four questionnaires.

POTENTIAL RISKS AND DISCOMFORTS

All of the procedures and equipment are standard and approved for their function. If there is an equipment malfunction, the major risk will be an inaccurate reading or no measurement. If this happens, the equipment will be repaired or replaced. The major discomfort may be that you perceive the study as frustrating and a disruption to normal life.

There may be risks or side effects which are unknown at this time.

ANTICIPATED BENEFITS TO SUBJECTS

You may or may not benefit by taking part in this study. If the Home Remote Monitoring is effective, those who receive it may have fewer trips to the hospital or emergency room; however this cannot be guaranteed. You should not expect your condition to improve as a result of taking part in this research.

COSTS

There is no cost to you for any of the services provided in the research. However, you will still be billed for your regular health care costs by your health care provider.

PAYMENT FOR PARTICIPATION

There is no payment for volunteering or participating in the research.

ALTERNATIVES TO PARTICIPATION

The alternative is not to participate in the research. Lack of participation will have no effect on your care, as the services in the research are in addition to your usual care.

CONFIDENTIALITY

Your identity will be kept secret so that no information collected on you can be discovered. You will be assigned a unique identifier at the beginning of the study that will be linked to your personal information. The identifier can only be accessed by authorized study staff and will be stored in a secure room to prevent access by unauthorized personnel. Authorized representatives of the U.S. Army Medical Research and Materiel Command and Western Institutional Review Board® (WIRB®) may see your information, but they are bound by rules of confidentiality not to reveal your identity to others.

USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION

By signing this consent form, you are authorizing the use and disclosure of individually identifiable information by Dr. Steven J. Berman and his research staff. Liberty Dialysis and any medical facility where you are hospitalized or treated in the emergency room are authorized to use and disclose this personal health information. Individually identifiable information collected will include: name, Social Security number, Medical Record number, Account numbers, Health Plan Beneficiary numbers, dates such as birth date, zip code, hospitalization information (including medical facility, admission, or discharge dates, diagnoses, procedures, and financial data), and information from emergency room visits (including medical facility, date, diagnoses, procedures, and financial data). Your information will be accessed after you consent to participate and will be updated periodically after each hospitalization and/or emergency room visit during the course of the study and for the 12 months following completion of the study. Your information will only be used and/or disclosed as described in this consent form and as permitted by state and federal laws.

The information we are collecting, including the personal health information listed above, will be maintained by Dr. Steven J. Berman for the length of the study and as required by the federal government. If any further research is planned that would include the use of your personal health information, you will be offered an opportunity to sign another consent form.

This consent form covers all information in your medical records at Liberty Dialysis, as well as your information in medical records and hospital information from any institution from which you receive medical care that is collected for this study. The consent form also covers information obtained from the nurse conducting the remote monitoring and questionnaires.

Your authorization to use your identifiable health information will not expire, even if you decide to withdraw from the study or if the study doctor withdraws you from the study. But at any time, you may cancel your authorization to use your identifiable information by providing written notice to the study doctor, Dr. Steven J. Berman, 2226 Liliha Street, Room B115, Honolulu, Hawaii 96817. When we receive this written notice, we will no longer use or disclose your identifiable health information, except where the law allows us to continue using this information. We are not to destroy or retrieve any of your health information that was created, used, or disclosed required for this study before we received your written notice of withdrawal.

Your medical record may contain information about AIDS or HIV infection, venereal disease, alcohol, drug abuse, mental health, or psychiatric services. By signing this consent form, you authorize treatment for access to the use and disclosure of this information if it is in the records used by members of the research team.

Some of the persons or groups that receive your study information may not be required to comply with federal privacy regulations, and your information may lose its federal privacy protection if those persons or groups disclose it.

REVIEW OF RESEARCH RECORDS

The individuals named above may disclose your medical records, this consent form, and the information about you created by this study to:

- The study sponsor (the Department of Defense U.S. Army Medical Research and Materiel Command);
- Federal, State, and local agencies having oversight over this research, such as the U.S. Food and Drug Administration (FDA), the U.S. Office for Human Research Protections (OHRP), the National Institutes of Health, etc.;
- Hawaii Pacific Health;
- The Western Institutional Review Board® (WIRB®) for purposes of overseeing the research study and making sure that your rights as a research subject are being protected.

RESEARCH-RELATED INJURY

Because of the nature of this study, we do not anticipate any illness or injury as a result of the study or procedures. There is no funding to pay for any medical expenses beyond your usual insurance benefits for any illness or injury that occurs during the time you are participating in this study. You will receive usual medical care as directed by your physician. If you do become ill or injured during the study, contact Dr. Steven J. Berman's research nurse through the Physicians Exchange, 808-524-2575, 24 hours a day, seven days a week.

PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. A decision not to participate will not affect your relationship with your doctor or Liberty Dialysis, or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

The study doctor or the sponsor may withdraw you from participating in this research at any time without your consent for any of the following reasons:

- if circumstances arise which warrant doing so (such as, not cooperating with the research team);
- if it is in your best interest;
- you do not later consent to any future changes that may be made in the study plan;
- or for any other reason.

NEW FINDINGS

You will be informed of any significant new findings developed during the course of the study that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs.

QUESTIONS

If you have any questions about your participation in this study, if at any time you feel you have had a research-related injury, or if you have questions, concerns, or complaints about the research, contact:

Steven J. Berman, M.D.
Room B115
2226 Liliha Street
Honolulu, Hawaii 96817
808-547-6208.

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read the information in this consent form (or it has been read to me). I have been given an opportunity to ask questions, and all of my questions have been answered to my satisfaction. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Name of Subject (printed)

_____ _____
Signature of Subject Date

_____
Name of Person Conducting Informed Consent Discussion (printed)

_____ _____
Signature of Person Conducting Informed Consent Discussion Date (same as subject's)

SIGNATURE OF WITNESS

My signature as witness certifies that the subject signed this consent form in my presence as his/her voluntary act and deed.

_____
Name of Witness (printed)

_____ _____
Signature of Witness Date (same as subject's)

APPROVED
AS MODIFIED
Jul 10, 2009
WIRB®

---------- **Use the following only if applicable** ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

_____
Name of Witness (printed)

_____ _____
Signature of Impartial Witness Date (same as subject's)

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

Copy to: Subject
Person Conducting Informed Consent Discussion
Witness
Impartial Witness

7. Study Advertisements

#6911937.0

Sponsored by the Department of Defense

H.O.P.E. Project

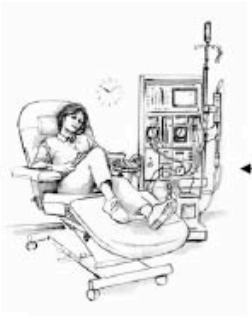
START
You are here

To participate in project
- Sign the Informed Consent

If you qualify you will be assigned to:
- Survey group, or
- Turtle group

Up to 24 Months

~~9 months~~:
Free!!!
Little to no risk!!!



Survey group

- Same dialysis schedule
- Project Assistant will come to dialysis unit to give you a short survey every other month.

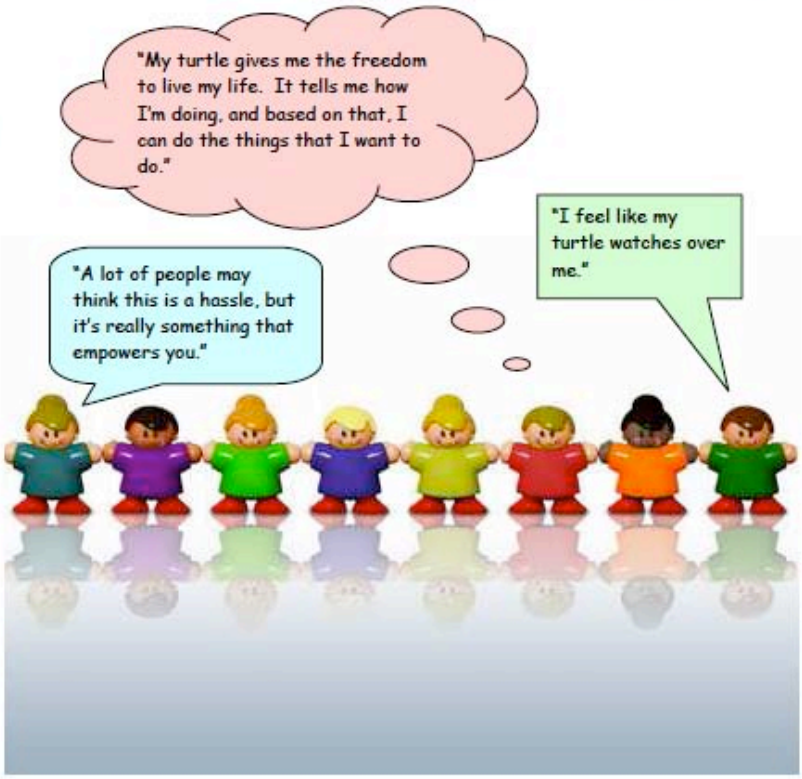
Turtle group

- Same dialysis schedule
- On your days off of dialysis, you check:
  - Blood pressure
  - Oxygen level
  - Weight
  - Blood sugar (if needed)
  - Answer a few questions about your health
- Your results will be sent to the project nurse, who will check them from her office.
- She will call you if any results are abnormal

Benefits

- You become an active member of your health care team.
- You may become more aware of small changes in your daily health.
- Your quality of life may get better.
- You may have fewer hospitalizations and/or emergency room visits.

Testimonials



Thank you!

By taking part in this study, you are making an important contribution to medical research, which may help improve the care of future dialysis patients.

8. HRPO Amendment and Continuing Review Acceptance Memorandum, dated July 29, 2009.

Gmail

Steven J. Berman MD <hopeprojecthawaii@gmail.com>

A-14200, Amendment and Continuing Review Acceptance Memorandum (Proposal Log Number 06167002, Award Number W81XWH-07-2-0064) (UNCLASSIFIED)

Duchesneau, Caryn L Ms CIV USA MEDCOM USAMRMC <Caryn.Duchesneau@us.army.mil> **Wed, Jul 29, 2009 at 6:49 AM**

To: sjberman@gmail.com

Cc: "Saiki, Stanley Dr Hui TAMC" <Stanley.Saiki@med.va.gov>, "Sawyer, Lisa M Ms CIV USA MEDCOM USAMRAA" <Lisa.Sawyer@amedd.army.mil>, jodi.bennett@amedd.army.mil, caryn.duchesneau@amedd.army.mil, "Wilberding, Julie A Dr CTR USA MEDCOM USAMRMC" <Julie.Wilberding@amedd.army.mil>, hopeprojecthawaii@gmail.com, brigit.ciccarello@tatrc.org, jeffrey.stephenson@tatrc.org, sanders@tatrc.org, karen.eaton@amedd.army.mil, "Hernandez, Latisa A Ms CTR USA MEDCOM USAMRMC" <Latisa.Hernandez@us.army.mil>, "Brosch, Laura R Dr CIV USA MEDCOM USAMRMC" <Laura.Brosch@us.army.mil>

Classification: UNCLASSIFIED
Caveats: NONE

SUBJECT: Amendment and Continuing Review Acceptance for the Protocol, "The Economic and Quality of Life Impact of Remote Technologies on High Risk Patients and Their Caregivers," Submitted by Steven J. Berman, MD, St. Francis Healthcare Foundation, Honolulu, Hawaii, Proposal Log Number 06167002, Award Number W81XWH-07-2-0064, HRPO Log Number A-14200

1. The U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) approved the subject protocol on 13 March 2008.

2. The HRPO received a continuing review report for the subject protocol on 21 November 2008. The Hawaii Pacific Health (HPH) Institutional Review Board (IRB) approved continuation of the protocol on 7 October 2008; this approval will expire on 6 October 2009.

3. The submitted continuing review report and supporting documentation have been reviewed by the HRPO and found to be in compliance with Federal, DOD, and U.S. Army human subjects protection requirements. The report and supporting documents are accepted.

4. This study is currently approved to enroll 30 subjects. As of the date of the continuing review report submission, the total number of subjects enrolled in this study was 28.

5. The HRPO received amendments for this no greater than minimal risk protocol that were approved by the HPH IRB. The amendments to the study included the following revisions:

a. Revised subject recruitment letter.

b. Addition of an Administrative Assistant, Heather Thomas.

c. Removal of James Reisen and Kathy Wooldridge from the study.

d. Subject protocol (Version 7, Dated October 3, 2008).

6. The changes proposed in the amendments do not pose any new or additional risks to participants beyond those identified in the previously approved protocol. The protocol amendments are accepted.

7. Please note the following reporting obligations:

a. Major modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the USAMRMC ORP HRPO for approval prior to implementation. All other amendments must be submitted with the continuing review report to the HRPO for acceptance.

b. All unanticipated problems involving risks to subjects or others, serious adverse events related to study participation, and deaths related to study participation must be reported promptly to the HRPO.

c. Any deviation to the subject protocol that affects the safety or rights of the subject and/or integrity of the study data must be reported promptly to the HRPO.

d. All modifications, deviations, unanticipated problems, adverse events, and deaths must also be reported at the time of continuing review of the protocol.

e. A copy of the continuing review report approved by the HPH IRB must be submitted to the HRPO as soon as possible after receipt of approval. It appears the next continuing review by the HPH IRB is due no later than 6 October 2009.

f. In addition, the current version of the protocol and consent form must be submitted along with the continuing review report and the HPH IRB approval notice for continuation of the protocol.

g. The final study report submitted to the HPH IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.

8. Do not construe this correspondence as approval for any contract funding. Only the Contracting Officer or Grants Officer can authorize expenditure of funds. It is recommended that you contact the appropriate contract specialist or contracting officer regarding the expenditure of funds for your project.

9. The HRPO point of contact for this study is Karen Eaton, MS, Human Subjects Protection Scientist, at 301-619-9268/Karen.m.eaton@us.army.mil.

10. The point of contact for this action is LaTisa Hernandez, PA, CCRC, Continuing Review Analyst, at 301-619-1029/LaTisa.Hernandez@us.army.mil.

CARYN L. DUCHESNEAU, CIP

Chief, Human Subjects Protection Review

Human Research Protection Office

Office of Research Protections

U.S. Army Medical Research and Materiel Command

Note: The official copy of this acceptance memo is housed with the protocol file at the Office of Research Protections, Human Research Protection Office, 504 Scott Street, Fort Detrick, MD 21702. Signed copies will be provided upon request.

Classification: **UNCLASSIFIED**
Caveats: NONE

9. Western IRB Approval Letter dated September 18, 2009.

WIRB®
(360) 252-2500
1-800-562-4789
FAX: (360) 252-2498

Western Institutional Review Board®

3535 SEVENTH AVENUE, SW, OLYMPIA, WA 98502-5010
P.O. BOX 12029, OLYMPIA, WA 98508-2029

Certificate of Approval

THE FOLLOWING WERE APPROVED:

INVESTIGATOR: Steven J. Berman M.D.
Room B115
2226 Liliha Street
Honolulu, Hawaii 96817

BOARD ACTION DATE: 9/18/2009
PANEL: 6
STUDY APPROVAL EXPIRES: 4/17/2010
STUDY NUM: 1107395
WIRB PRO NUM: 20090577
INVEST NUM: 148923
WO NUM: 1-573785-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Annually

SPONSOR: Department of Defense
PROTOCOL NUM: None
AMD. PRO. NUM:
TITLE:
THE ECONOMIC AND QUALITY OF LIFE IMPACT OF REMOTE TECHNOLOGIES ON HIGH RISK PATIENTS AND THEIR CAREGIVERS

APPROVAL INCLUDES:
Revised Protocol (09-14-2009) Version 10

WIRB APPROVAL IS GRANTED SUBJECT TO:

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789

This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB). OHRP/FDA parent organization number IORG 0000432, IRB registration number IRB00000533. WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Full AAHRPP Accreditation

Theodore D. Schultz, J.D., Chairman

9/21/2009
(Date)

This document electronically reviewed and approved by Schultz, Ted on 9/21/2009 10:55:03 AM PST. For more information call Client Services at 1-360-252-2500

Page 1 of 3

Board Action: 9/18/2009, Study: 1107395

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

- H.O.P.E. Project, Room B115, 2226 Liliha Street, Honolulu, Hawaii 96817

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

3. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate. (Due to the unique circumstances of research conducted at international sites outside the United States and Canada where WIRB approved materials are translated into the local language, the following requirements regarding consent forms bearing the WIRB approval stamp and regarding certification of translations are not applicable.)

    a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.

    b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB.

    c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

4. Obtain pre-approval from WIRB for changes in research.

5. Obtain pre-approval from WIRB for any planned deviations that could adversely affect the rights, safety or welfare of subjects, or the integrity of the research data and any changes in the research activity. The only exception is when changes are necessary to eliminate apparent immediate hazards to subjects. Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days.

6. Promptly report to WIRB all unanticipated problems (adverse events, protocol deviations and violations and other problems) that meet all of the following criteria:

    a. Unexpected (in terms of nature, severity or frequency);

    b. Related or possibly related to participation in the research; and

    c. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

    Please go to www.wirb.com for complete definitions and forms for reporting.

7. Provide reports to WIRB concerning the progress of the research, when requested.

8. Ensure that prior to performing study-related duties, each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

Contact	Company Name
Christine Nelson	Hawaii Pacific Health
Steven J. Berman M.D.	St. Francis Healthcare Foundation of Hawaii - H.O.P.E. Project
Stanley Saiki M.D.	Department of Defense
Heather Thomas	St. Francis Healthcare Foundation of Hawaii - H.O.P.E. Project

10. HRPO Amendments Approval Memorandum dated September 25, 2009.

Gmail by Google

Steven J. Berman MD <hopeprojecthawaii@gmail.com>

A-14200, Amendments Approval Memorandum (Proposal Log Number 06167002, Award Number W81XWH-07-2-0064) (UNCLASSIFIED)

Duchesneau, Caryn L Ms CIV USA MEDCOM USAMRMC <Caryn.Duchesneau@us.army.mil> **Fri, Sep 25, 2009 at 1:54 PM**

To: Steven Berman <sjberman@gmail.com>
Cc: "Bennett, Jodi H Ms CIV USA MEDCOM USAMRMC" <Jodi.Bennett@us.army.mil>, "Ciccarello, Brigit Ms GENEVA FOUNDATION" <Brigit.Ciccarello@tatrc.org>, carmen.sanders@tatrc.org, Heather Thomas <hopeprojecthawaii@gmail.com>, stanley.saiki@tatrc.org, "Brosch, Laura R Dr CIV USA MEDCOM USAMRMC" <Laura.Brosch@us.army.mil>, "Duchesneau, Caryn L Ms CIV USA MEDCOM USAMRMC" <Caryn.Duchesneau@us.army.mil>, "Wilberding, Julie A Dr CTR USA MEDCOM USAMRMC" <Julie.Wilberding@amedd.army.mil>, "Eaton, Karen M Ms CTR USA MEDCOM USAMRMC" <Karen.M.Eaton@us.army.mil>, "Sawyer, Lisa M Ms CIV USA MEDCOM USAMRAA" <Lisa.Sawyer@amedd.army.mil>, jeffrey.stephenson@tatrc.org

Classification: **UNCLASSIFIED**
Caveats: NONE

SUBJECT: Amendments for the Protocol, "The Economic and Quality of Life Impact of Remote Technologies on High Risk Patients and Their Caregivers," Submitted by Steven J. Berman, MD, St. Francis Healthcare Foundation, Honolulu, Hawaii, Proposal Log Number 06167002, Award Number W81XWH-07-2-0064, HRPO Log Number A-14200

1. The subject protocol received final approval by the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) on 13 March 2008.

2. Amendments to this no greater than minimal risk protocol were received by the HRPO on 17 July 2009. The amendments were approved by the Western Institutional Review Board (WIRB) on 10 July 2009 and 18 September 2009.

3. The amendments allow the following changes:

a. Change in Institutional Review Board of Record from Hawaii Pacific Health Institutional Review Board (HPH IRB) to the WIRB.

b. Addition of Phase 2 of the study which decreases the number of intervention groups from the 3 groups described in Phase 1 (usual care, remote technology intervention, or home health aide intervention) to 2 groups for Phase 2 (usual care or remote technology).

c. Increased tracking of Phase 1 (pilot study) patients from 9 months to 24 months.

d. Increased number of subjects to 50.

e. Administrative staff changes.

f. Addition of promotional flyers to be used in subject recruitment.

g. Removal of references and reporting requirements to HPH IRB.

4. The changes proposed in the amendments have been reviewed by the HRPO and found to be acceptable. The protocol amendments are approved (protocol version 10, dated 14 September 2009).

5. The Principal Investigator remains responsible for fulfilling reporting requirements to the HRPO as outlined in the initial approval memo dated 13 March 2008.

6. Do not construe this correspondence as approval for any contract funding. Only the Contracting Officer or Grants Officer can authorize expenditure of funds. It is recommended that you contact the appropriate contract specialist or contracting officer regarding the expenditure of funds for your project.

7. The HRPO point of contact for this action is Karen M. Eaton, MS, Human Subjects Protection Scientist, at extension 301-619-9268/Karen.m.eaton@us.army.mil.

CARYN L. DUCHESNEAU, CIP

Chief, Human Subjects Protection Review

Human Research Protection Office

Office of Research Protections

U.S. Army Medical Research and Materiel Command

Note: The official copy of this approval memo is housed with the protocol file at the Office of Research Protections, Human Research Protections Office, 504 Scott Street, Fort Detrick, MD 21702. Signed copies will be provided upon request.

Classification: **UNCLASSIFIED**
Caveats: NONE

11. SF36

Your Health in General

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully, and mark an ☒ in the one box that best describes your answer. ***Thank you for completing this survey!***

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b. <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c. Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d. Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3
e. Climbing <u>one</u> flight of stairs	☐ 1	☐ 2	☐ 3
f. Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g. Walking <u>more than a mile</u>	☐ 1	☐ 2	☐ 3
h. Walking <u>several hundred yards</u>	☐ 1	☐ 2	☐ 3
i. Walking <u>one hundred yards</u>	☐ 1	☐ 2	☐ 3
j. Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. **During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?**

None	Very mild	Mild	Moderate	Severe	Very Severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. **During the past <u>4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

☐1 ☐2 ☐3 ☐4 ☐5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	☐1	☐2	☐3	☐4	☐5
b. I am as healthy as anybody I know	☐1	☐2	☐3	☐4	☐5
c. I expect my health to get worse	☐1	☐2	☐3	☐4	☐5
d. My health is excellent	☐1	☐2	☐3	☐4	☐5

THANK YOU FOR COMPLETING THESE QUESTIONS!

12. HUI

HUI®

HEALTH UTILITIES INDEX®

INTERVIEWER-ADMINISTERED QUESTIONNAIRE

(US English - Self-assess)

Not for quotation or distribution without permission. All copies of this questionnaire should include a cover sheet which clearly acknowledges that it is a Health Utilities Index questionnaire developed by Health Utilities Inc. (see prototype attached).

Do not use this questionnaire without written approval from Health Utilities Inc. This questionnaire is one of many HUI® data collection instruments, and may not be the most appropriate for your study.

HUI23S2US.40Q

HEALTH UTILITIES INDEX MARK 2 AND MARK 3 (HUI2/3) 40-ITEM QUESTIONNAIRE FOR INTERVIEWER-ADMINISTERED, SELF-ASSESSED "TWO WEEK" HEALTH STATUS ASSESSMENT

by
WJ Furlong, DH Feeny and GW Torrance
Health Utilities Inc., Dundas ON Canada
August 2004

Permission for use of this document is limited to one study and must be obtained in writing from:

Health Utilities Inc. (HUInc.)
88 Sydenham Street
Dundas ON, Canada L9H 2V3
Telephone (905) 525-9140, extension 22389 / 22377
Fax (905) 627-7914
furlongb@mcmaster.ca
http://www.healthutilities.com

HEALTH UTILITIES INDEX

Notes to researchers regarding the 40-item questionnaire for
interviewer-administered, self-assessed
"two week" health status assessment

The attached 40-item interviewer-administered questionnaire has been designed to ask the minimum number of questions, either in-person or by telephone, required to classify a subject's health status according to the classification systems of both Health Utilities Index Mark 2 and Mark 3 (HUI2 and HUI3). Question 41 is not an HUI® question but is included in this questionnaire because it is often useful to collect this information in health status measurement surveys. **Please note that respondents are to be encouraged to answer all appropriate questions. "Don't know" and "Refused" responses result in missing data and you will not be able to calculate the HUI utility scores for respondents with missing answers.**

This version of the questionnaire is phrased to elicit responses from a wide variety of subjects, aged 8 years and older, about their health status during the past 2 weeks, from their own perspective. Other versions are available to facilitate administration to proxy respondents (eg., family members and health professionals) and to focus questions on other assessment periods. The "current" health focus is often used in clinical studies and economic evaluations of health care programs, in which the concern is to monitor health changes due to treatment. The "usual" health focus has been used in population health surveys, where short-term illnesses like colds are not the major concern. Please contact HUInc to obtain copies of other versions of the questionnaire.

This questionnaire includes a prototype cover sheet of variables that are typically important for identifying each interview (eg., subject ID number and date). All copies of the questionnaire should be clearly marked as a HUInc. questionnaire.

For further information about the HUI® and to obtain a copy of the algorithm[1] for coding responses from the 40-item interviewer-administered questionnaire, please contact the following (and refer to questionnaire HUI23S2US.40Q: 2002-09):

William (Bill) Furlong
Health Utilities Inc. (HUInc)
88 Sydenham Street, Dundas ON, Canada L9H 2V3
Telephone (905) 525-9140, extension 22389
Fax (905) 627-7914
furlongb@mcmaster.ca
http://www.healthutilities.com

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1. Furlong WJ, Feeny DH, Torrance GW. Health Utilities Index: Algorithm for determining Mark 2 (HUI2) / Mark 3 (HUI3) health status classification levels, health states, health-related quality of life scores, and single attribute level utility scores for 40-item interviewer-administered health status questionnaires. Health Utilities Inc., unpublished document; February 1, 1999.

HUI2352US.40Q
HEALTH UTILITIES INDEX MARK 2 AND MARK 3 (HUI2/3)
40-ITEM QUESTIONNAIRE FOR
INTERVIEWER-ADMINISTERED, SELF-ASSESSED
"TWO WEEK" HEALTH STATUS ASSESSMENT

STUDY TITLE:_____

ID NUMBER OF SUBJECT:_____

NAME OF SUBJECT:_____

NAME OF INTERVIEWER:_____

DATE OF INTERVIEW: _____

START TIME: _____ a.m./p.m.

END TIME:_____ a.m./p.m.

CONFIDENTIAL (when completed)

For office use only:

Name of person who collected completed questionnaire:_____

Date completed questionnaire received by office:_____

Health Utilities Inc. (HUInc)
88 Sydenham Street
Dundas ON, Canada L9H 2V3
Telephone (905) 525-9140, extension 22389 / 22377
Fax (905) 627-7914
furlongb@mcmaster.ca
http://www.healthutilities.com

HUI23S2US.40Q
HEALTH UTILITIES INDEX MARK 2 AND MARK 3 (HUI2/3)
40-ITEM QUESTIONNAIRE FOR
INTERVIEWER-ADMINISTERED, SELF-ASSESSED
"TWO WEEK" HEALTH STATUS ASSESSMENT

The next set of questions ask about various aspects of your health. When answering these questions we would like you to think about your health and your ability to do things on a day-to-day basis, during the past two weeks. To define the 2 week period, please think about what the date was 2 weeks ago and recall the major events that you have experienced during this period. Please focus your answers on your abilities, disabilities and how you have felt during the past 2 weeks.

You may feel that some of these questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar; please excuse the apparent overlap and answer each question independently.

All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities and feelings.

Interviewer:
For each question, read the entire sentence as written on the left-hand side of the page following the question number, emphasizing the underlined words or words in italics, if any. Do not read the response options listed down the right-hand margin of the page except if listed as part of the question (e.g., Q26, Q31, etc.). Do not read the "Don't know" and "Refused" responses. Encourage respondents to answer each question to the best of their recollection. The answer given by the respondent to each question should be clearly marked in the circle/box beside the one appropriate answer listed in the right hand margin of the question page.

VISION

1	During the past 2 weeks, have you been able to see well enough to read ordinary newsprint *without* glasses or contact lenses?	O Yes → **Go to 4** O No O Don't know O Refused
2	Have you been able to see well enough to read ordinary newsprint *with* glasses or contact lenses?	O Yes → **Go to 4** O No O Don't know / Didn't wear glasses or contact lenses O Refused
3	During the past 2 weeks, have you been able to see at all?	O Yes O No → **Go to 6** O Don't know O Refused
4	During the past 2 weeks, have you been able to see well enough to recognize a friend on the other side of the street *without* glasses or contact lenses?	O Yes → **Go to 6** O No O Don't know O Refused

5	Have you been able to see well enough to recognize a friend on the other side of the street *with* glasses or contact lenses?	O Yes O No O Don't know / Didn't wear glasses or contact lenses O Refused

HEARING

6	During the past 2 weeks, have you been able to hear what is said in a group conversation with at least three other people *without* a hearing aid?	O Yes → **Go to 11** O No O Don't know O Refused
7	Have you been able to hear what is said in a group conversation with at least three other people *with* a hearing aid?	O Yes → **Go to 9** O No O Don't know / Didn't wear a hearing aid O Refused
8	During the past 2 weeks, have you been able to hear at all?	O Yes O No → **Go to 11** O Don't know O Refused
9	During the past 2 weeks, have you been able to hear what is said in a conversation with one other person in a quiet room *without* a hearing aid?	O Yes → **Go to 11** O No O Don't know O Refused
10	Have you been able to hear what is said in a conversation with one other person in a quiet room *with* a hearing aid?	O Yes O No O Don't know / Didn't wear a hearing aid O Refused

SPEECH

11	During the past 2 weeks, have you been able to be understood *completely* when speaking your own language with people who do not know you?	O Yes → **Go to 16** O No O Don't know O Refused
12	Have you been able to be understood *partially* when speaking with people who do not know you?	O Yes O No O Don't know O Refused

13	During the past 2 weeks, have you been able to be understood *completely* when speaking with people who know you well?	O Yes → **Go to 16** O No O Don't know O Refused
14	Have you been able to be understood *partially* when speaking with people who know you well?	O Yes → **Go to 16** O No O Don't know O Refused
15	During the past 2 weeks, have you been able to speak at all?	O Yes O No O Don't know O Refused

GETTING AROUND

16	During the past 2 weeks, have you been able to bend, lift, jump and run *without difficulty* and *without help or equipment* of any kind?	O Yes → **Go to 24** O No O Don't know O Refused
17	Have you been able to walk around the neighborhood *without difficulty* and *without help or equipment* of any kind?	O Yes → **Go to 24** O No O Don't know O Refused
18	Have you been able to walk around the neighborhood *with difficulty* but *without help or equipment* of any kind?	O Yes → **Go to 24** O No O Don't know O Refused
19	During the past 2 weeks, have you been able to walk at all?	O Yes O No → **Go to 22** O Don't know O Refused
20	Have you needed mechanical support, such as braces or a cane or crutches, to be able to walk around the neighborhood?	O Yes O No O Don't know O Refused
21	Have you needed the help of another person to walk?	O Yes O No O Don't know O Refused

22	Have you needed a wheelchair to get around the neighborhood?	O Yes O No O Don't know O Refused
23	Have you needed the help of another person to get around in the wheelchair?	O Yes O No O Don't know O Refused

HANDS AND FINGERS

24	During the past 2 weeks, have you had the *full use* of both hands and ten fingers?	O Yes → **Go to 28** O No O Don't know O Refused
25	Have you needed the help of another person because of limitations in the use of your hands or fingers?	O Yes O No → **Go to 27** O Don't know O Refused
26	Have you needed the help of another person with some tasks, most tasks, or all tasks?	O Some tasks O Most tasks O All tasks O Don't know O Refused
27	Have you needed special equipment, for example special tools to help with dressing or eating, because of limitations in the use of your hands or fingers?	O Yes O No O Don't know O Refused

SELF-CARE

28	During the past 2 weeks, have you been able to eat, bathe, dress and use the toilet without difficulty?	O Yes → **Go to 31** O No O Don't know O Refused
29	Have you needed the help of another person to eat, bathe, dress or use the toilet?	O Yes O No O Don't know O Refused
30	Have you needed special equipment or tools to eat, bathe, dress or use the toilet?	O Yes O No O Don't know O Refused

FEELINGS

31	During the past 2 weeks, have you been feeling happy or unhappy?	O Happy O Unhappy → **Go to 33** O Don't know O Refused
32	Would you describe yourself as having felt: a) happy and interested in life, or b) somewhat happy?	O a → **Go to 34** O b → **Go to 34** O Don't know O Refused
33	Would you describe yourself as having felt: a) somewhat unhappy b) very unhappy c) so unhappy that life is not worthwhile	O a O b O c O Don't know O Refused
34	During the past 2 weeks, did you ever feel fretful, angry, irritable, anxious or depressed?	O Yes O No → **Go to 37** O Don't know O Refused
35	How often did you feel fretful, angry, irritable, anxious or depressed: rarely, occasionally, often, or almost always?	O Rarely O Occasionally O Often O Almost always O Don't know O Refused
36	During the past 2 weeks did you feel *extremely* fretful, angry, irritable, anxious or depressed; to the point of needing professional help?	O Yes O No O Don't know O Refused

MEMORY

37	How would you describe your ability to remember things, during the past 2 weeks: (a) able to remember most things (b) somewhat forgetful (c) very forgetful (d) unable to remember anything at all?	O a O b O c O d O Don't know O Refused

THINKING

38	How would you describe your ability to think and solve day to day problems, during the past 2 weeks: (a) able to think clearly and solve problems (b) had a little difficulty (c) had some difficulty (d) had a great deal of difficulty (e) unable to think or solve problems?	O a O b O c O d O e O Don't know O Refused

PAIN AND DISCOMFORT

39	Have you had any trouble with pain or discomfort, during the past 2 weeks?	O Yes O No → **Go to 41** O Don't know O Refused
40	How many of your activities, during the past 2 weeks, were limited by pain or discomfort: none, a few, some, most, all?	O None O A few O Some O Most O All O Don't know O Refused
41	Overall, how would you rate your health during the past 2 weeks? (a) excellent (b) very good (c) good (d) fair (e) poor	O a O b O c O d O e O Don't know O Refused

Thank you. That ends this set of questions.

TIME FINISHED: _____ **a.m. / p.m.**

13. Western IRB Continuing Review Approval Letter dated March 31, 2010.

WIRB®

Western Institutional Review Board ®

Certificate of Approval

(360) 252-2500
1-800-562-4789
FAX: (360) 252-2498

3535 SEVENTH AVENUE, SW, OLYMPIA, WA 98502-5010
P.O. BOX 12029, OLYMPIA, WA 98508-2029

THE FOLLOWING WERE APPROVED:

INVESTIGATOR: Steven J. Berman M.D.
Room B115
2226 Liliha Street
Honolulu, Hawaii 96817

BOARD ACTION DATE: 3/26/2010
PANEL: 6
STUDY APPROVAL EXPIRES: 4/17/2011
STUDY NUM: 1107395
WIRB PRO NUM: 20090577
INVEST NUM: 148923
WO NUM: 1-602074-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Annually

SPONSOR: Department of Defense
PROTOCOL NUM: None
AMD. PRO. NUM:
TITLE:
THE ECONOMIC AND QUALITY OF LIFE IMPACT OF REMOTE TECHNOLOGIES ON HIGH RISK PATIENTS AND THEIR CAREGIVERS

APPROVAL INCLUDES:
Study and Investigator for an additional continuing review period. This approval expires on the date noted above.

WIRB APPROVAL IS GRANTED SUBJECT TO:

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789

This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB), OHRP/FDA parent organization number IORG 0000432, IRB registration number IRB00000533. WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Full AAHRPP

Theodore D. Schultz, J.D., Chairman

3/31/2010
(Date)

This document electronically reviewed and approved by Ennever, John on 3/31/2010 9:25:12 PM PST. For more information call Client Services at 1-360-252-2500

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

- H.O.P.E. Project, Room B115, 2226 Liliha Street, Honolulu, Hawaii 96817

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

3. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate. (Due to the unique circumstances of research conducted at international sites outside the United States and Canada where WIRB approved materials are translated into the local language, the following requirements regarding consent forms bearing the WIRB approval stamp and regarding certification of translations are not applicable.)

    a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.

    b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB.

    c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

4. Obtain pre-approval from WIRB for changes in research.

5. Obtain pre-approval from WIRB for any planned deviations that could adversely affect the rights, safety or welfare of subjects, or the integrity of the research data and any changes in the research activity. The only exception is when changes are necessary to eliminate apparent immediate hazards to subjects. Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days.

6. Promptly report to WIRB all unanticipated problems (adverse events, protocol deviations and violations and other problems) that meet all of the following criteria:

    a. Unexpected (in terms of nature, severity or frequency);

    b. Related or possibly related to participation in the research; and

    c. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

    Please go to www.wirb.com for complete definitions and forms for reporting.

7. Provide reports to WIRB concerning the progress of the research, when requested.

8. Ensure that prior to performing study-related duties, each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

Contact	Company Name
Christine Nelson	Hawaii Pacific Health
Steven J. Berman M.D.	St. Francis Healthcare Foundation of Hawaii - H.O.P.E. Project
Stanley Saiki M.D.	Department of Defense
Heather Thomas	St. Francis Healthcare Foundation of Hawaii - H.O.P.E. Project

14. HRPO Amendment and Continuing Review Acceptance Memorandum dated May 18, 2010.

Gmail

Steven J. Berman MD <hopeprojecthawaii@gmail.com>

RE: Continuing Review Question (W81XWH-07-2-0064) (UNCLASSIFIED)

1 message

Anderson, Natasha N CTR US USA MEDCOM USAMRMC <Natasha.Anderson@amedd.army.mil> **Tue, May 18, 2010 at 3:27 AM**
To: Tamami Harada <hopeprojecthawaii@gmail.com>

Classification: UNCLASSIFIED
Caveats: NONE

Hi Heather

For Dr. Berman protocol entitled "The Economic and Quality of Life Impact of Remote Technologies on High Risk Patients and Their Caregivers" w received the continuing review documents on April 7, 2010. The next CR is due in April 2011. HRPO will send out a email reminder of next year.

Kind regards,

Natasha

Natasha N. Anderson, BS
Continuing Review Analyst (AMDEX Corporation)
Human Research Protection Office (HRPO)
Office of Research Protections (ORP)
U.S. Army Medical Research & Material Command (USAMRMC)
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Commanding General
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RPH/Natasha N. Anderson, BS
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Frederick, Maryland 21702-5012

-----Original Message-----
From: Tamami Harada [mailto:hopeprojecthawaii@gmail.com]
Sent: Monday, May 17, 2010 9:11 PM
To: Anderson, Natasha N CTR US USA MEDCOM USAMRMC
Subject: Continuing Review Question (W81XWH-07-2-0064)

Hi Natasha,

When is the next Continuing Review due for our research project? I want to make sure that we put it in our schedule. Will HRPO contact us about it when it's closer to the due date?

Thank you for your help.

Heather Thomas
--
H.O.P.E. Project
2226 Liliha Street, B115
Honolulu, HI 96817
Phone: (808) 547-6761
Fax: (808) 547-6932

Classification: UNCLASSIFIED
Caveats: NONE